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117TH CONGRESS
2D SESSION

H. R. 8405

To preserve access to abortion medications.

IN THE HOUSE OF REPRESENTATIVES

JULY 18, 2022

Ms. BUSH (for herself, Mr. BEYER, Ms. OMAR, Ms. JACKSON LEE, Ms. MCCOLLUM, and Ms. NORTON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To preserve access to abortion medications.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Protecting Access to Medication Abortion Act''.

SEC. 2. MODIFICATION OF REMS.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall require the responsible person involved to submit a proposal under subsection (g)(4)(A) of section 505–1 of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 355–1) to modify the risk evaluation and mitigation strategy under such section that applies to mifepristone so that—

(1) the in-person dispensing requirement is removed from such risk evaluation and mitigation strategy;

(2) patients may access prescriptions for such drug via telehealth; and

(3) all pharmacies that are certified to dispense such drug are permitted to, at minimum, dispense and mail such drug to patients.

(b) MODIFICATIONS.—Nothing in subsection (a) shall be construed to prevent the Secretary from approving a modification to the risk evaluation and mitigation strategy for mifepristone based on sound scientific evidence and in accordance with section 505–1(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(h)). Any modifications to such risk evaluation and mitigation strategy made after the proposal to modify required pursuant to subsection (a) shall be in accordance with the requirements under paragraphs (1), (2), and (3) of such subsection, unless the Secretary, based on sound scientific evidence and in accordance with section 505–1 of such Act (21 U.S.C. 355–1), determines that a risk evaluation and

mitigation strategy for mifepristone is no longer necessary.

(c) CLARIFICATION.—Nothing in subsection (a) shall be construed to limit the authority of the Secretary to impose the requirements described in paragraphs (1), (2), and (3) of such subsection to a risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) for any drug other than mifepristone.

(d) DEFINITION.—In this section, the term ''mifepristone'' means mifepristone that is—

(1) approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(2) indicated for medical abortion; and

(3) subject to a risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1).

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